

## **RPM Plus Participation in Tanzania President's Malaria Initiative (PMI) Year 2 Consultative Meeting May, 30 - 31, 2006: Trip Report**

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Strategic Objective 7

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## **About RPM Plus**

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

## **Recommended Citation**

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## **Key Words**

Malaria, Tanzania, PMI

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## **ACRONYMS**

ACT	Artemisinin-based Combination Therapy
ADDO	Accredited Drug Dispensing Outlet
ADR	Adverse Drug Reaction
AFRO	Africa Regional Office
ASSESS	Access to Clinical and Community Maternal, Neonatal and Women's Health Services
CDC	US Centers for Disease Control
ECSA	East, Central and Southern Africa
M&E	Monitoring and Evaluation
MAC	Malaria Action Coalition
MOHSW	Ministry of Health & Social Welfare
MSD	Medical Stores Department
MSH	Management Sciences for Health
NMCP	National Malaria Control Program
PMI	President's Malaria Initiative
REDSO	Regional Economic Development Services Office
RPM Plus	Rational Pharmaceutical Plus Program
TFDA	Tanzania Food & Drugs Authority
USAID	United States Agency for International Development
WHO	World Health Organization

## **BACKGROUND**

Management Sciences for Health's (MSH) Rational Pharmaceutical Management Plus (RPM Plus) Program has received funds from USAID to develop strategies to implement malaria policies and to provide technical assistance in pharmaceutical management issues for malaria. RPM Plus is a key technical partner in the USAID Malaria Action Coalition (MAC), a partnership among four technical partners: The World Health Organization (WHO), working primarily through its Africa Regional Office (AFRO), the US Centers for Disease Control (CDC), the ACCESS Program of JHPIEGO and RPM Plus.

RPM Plus is currently providing technical support to Tanzania activities geared towards achieving smooth implementation of the country's new malaria treatment policy. The implementation of these activities is through funding from the USAID Regional Economic Development Services Office for East, Central and Southern Africa (REDSO/ECSA) and more recently from the U.S. President's Malaria Initiative (PMI) in Tanzania.

RPM Plus Tanzania activities under year one PMI funding include:

- Private sector subsidized ACT delivery through the Accredited Drug Dispensing Outlet (ADDO) program
- Technical support provision to the Medical Stores Department to achieve an uninterrupted supply of ACTs to health facilities
- Support to the Tanzania Food and Drug Authority (TFDA) to improve adverse drug reaction monitoring and establish systems to detect unintentional exposure to artemether-lumefantrine in pregnancy.

The National Malaria Control Program (NMCP) of the Ministry of Health and Social Welfare (MOHSW) expects that support to the above activities within the overall malaria control framework will achieve improved pharmaceutical management systems/activities and enhance implementation of the new policy.

## **Purpose of Trip**

Gladys Tetteh traveled to Dar es Salaam, Tanzania to attend the US President's Malaria Initiative Year 2 Consultative Meeting in conjunction with Romuald Mbwas, RPM Plus Senior Technical Advisor based in Dar es Salaam. The meeting was held from May 30 – 31, 2006. The goal of the meeting was for USAID, the Ministry of Health and Social Welfare, Tanzania and all stakeholders involved in malaria control and those implementing PMI activities in Tanzania to review PMI year 1 progress and to discuss plans for PMI year 2 activities.

## **Scope of Work**

The scope of work for Gladys Tetteh and Romuald Mbwasí was to:

- Attend PMI Year 2 Consultative Meeting to review Year One progress and plan for Year Two activities
- Review RPM Plus Malaria (REDSO) activity progress
- Provide an arrival briefing and/or departure debriefing to USAID

## **ACTIVITIES**

### **Attend PMI Year 2 Consultative Meeting to review Year One progress and plan for Year Two activities**

Romuald Mbwasi and Gladys Tetteh attended the PMI consultative meeting on behalf of RPM Plus. Inputs were made into malaria case management discussions. A presentation made by Dr. Mbwasi on the “*Distribution of ACTs through a Private Sector Accredited Drug Dispensing Outlets (ADDO)*” highlighted the background to the ADDO initiative in response to the overall problem – how to increase access to and rational use of essential quality medicines? The presentation encouraged PMI investment in ADDOs as a pragmatic way of increasing access to quality antimalarial medicines including artemisinin-based combination therapies (ACTs). The current status of ADDOs in Tanzania was described as well as progress given on RPM Plus year one PMI activities (*see attached presentation*). Proposed strategies for ACT delivery through the ADDOs include the following:

- Support national authorities for ACT deregulation
- Orient ADDO outlets and local stakeholders to implement new malaria policy
- Work with NMCP to implement communication strategy for ADDO
- Develop ACT distribution with private wholesalers
- Work with MOHSW/NMCP and PMI team to develop a pricing policy/mechanism of ACT in ADDOs
- Work with TFDA/NMCP to strengthen ADDO M&E and inspection systems and develop ACTs tracking system at all levels of delivery

In line with the laid out strategies, activities proposed for RPM Plus year 2 funding under PMI include:

- Consolidation of ACT delivery in ADDO outlets and expansion to new ADDO outlets for rest of districts in Morogoro region.
- Development of M&E infrastructure for the ACTs in ADDO program
- Support TFDA in developing and implementing a comprehensive national ADDO roll out strategy

These activities will be detailed in a workplan for year 2 yet to be developed by RPM Plus.

### **Review RPM Plus Malaria (REDSO) activity progress**

A telephone discussion was held with RPM Plus Senior Program Associate, Salama Mwakis, and RPM Plus Consultant, Dr. Catherine Adegoke to discuss progress of an ongoing RPM Plus-supported MOHSW workshop for training manual development in Morogoro, Tanzania. The workshop was scheduled to end on June 2, 2006 and had already achieved many outputs including the development of two training manuals (for National Level Pharmacists and for Dispensers at District Hospitals/Health Centers/Dispensaries) and the development of a proposal for training of pharmaceutical management staff in support of ACT policy implementation.

Trainings at the national and zonal level are to receive financial and technical support from USAID (REDSO) through RPM Plus and are planned to begin in the first week of July, 2006.

**Provide an arrival briefing and/or departure debriefing to USAID**

Brief discussions on RPM Plus activities were held with Dr. Rene Salgado (USAID PMI focal point) and Ms. Pamela White (Country Director, USAID Tanzania). The draft concept paper, detailing RPM Plus's scope of work under PMI for increasing access to the ADDOs, needs to be finalized and submitted. This has subsequently been submitted (*see Annex*).



## **NEXT STEPS**

### **Immediate Follow-up Activities**

- Finalize recruitment of Senior Program Associate by MSH Tanzania to fast track the implementation of RPM Plus PMI year one activities
- Continued discussions with Dr. Salgado, PMI focal point, Dr. Patrick Kachur (CDC) and the NMCP to ensure smooth implementation of RPM Plus activities

## **ANNEX 1. PMI CONSULTATIVE MEETING AGENDA**

### **PMI Year 2 Consultative Meeting May 30th and 31st, 2006**

#### **Day One**

8:00 – 8:30	Registration
8:30 – 8:45	President's Malaria Initiative - Goals and Objectives Charles Llewellyn
8:45 – 9:00	"Building on Success" Pamela White Director USAID Tanzania Mission
9:00 – 9:15	Welcoming Remarks Mr. Michael L. Retzer U.S. Ambassador to the United Republic of Tanzania
9:15 – 9:30	Opening Remarks Hon. Dr. Aisha Omari Kigoda, MP MOHSW – Deputy Minister
	SHORT BREAK TO LET GUESTS DEPART
9:30 – 10:00	The National Malaria Control Programme Dr. Alex Mwita Manager National Malaria Control Programme Ministry of Health and Social Welfare
10:00 – 10:30	Coffee Break
10:30 – 10:35	Methodology for the Workshop Rene Salgado Facilitator
10:35 – 10:50	IMPROVING PREVENTION - 1 Insecticide Treated Nets (ITNs) The Tanzania National Voucher Scheme
10:50 – 11:05	The Tanzania National Voucher Scheme (TNVS) –

	Expansion to Infants
11:05 – 12:00	DISCUSSION AND SUMMARY - TNVS Expansion
12:00 – 12:15	The Tanzania National Voucher Scheme – “Safety Net”
12:15 – 13:00	DISCUSSION AND SUMMARY - TNVS – Safety Net
13:00 – 14:00	Lunch
14:00 – 14:15	LLIN Technology transfer Romanus Mtung'e ITN Director PSI Tanzania
14:15 – 14:45	DISCUSSION AND SUMMARY – LLIN Technology Transfer
14:45 – 15:00	The Tanzania National Voucher Scheme – Communication/Behavior Change Strategy Romanus Mtung'e ITN Director PSI Tanzania
15:00 – 15:30	DISCUSSION AND SUMMARY - TNVS – Communication/Behavior Change Strategy
15:30 – 16:00	Coffee Break
16:00 – 16:30	IMPROVING PREVENTION 2 Epidemic Response, Indoor Residual Spraying and Larviciding. Dr. Renata Mandike Dr. Azma Simba Gerry Killeen
16:30 -17:00	DISCUSSION AND SUMMARY – Epidemic Response, IRS and Larviciding
17:00 – 17:10	Summary of day's events

## **Day Two**

8:30 – 8:45	IMPROVING PREVENTION 3 Intermittent Preventive Treatment ACCESS
8:45 – 9:15	DISCUSSION AND SUMMARY – Intermittent Preventive Treatment
9:15 – 9:30	IMPROVING CASE MANAGEMENT 1 Improving diagnosis – RDTs Dr. Fabrizio Molteni NMCP – Italian Cooperation
9:30 – 9:50	DISCUSSION AND SUMMARY – Improving diagnosis -- RDTs
9:50 – 10:15	Improving Treatment A -- ACT Roll Out – Training, ZTCs, medical stores and quality assurance Dr. Mafungo Marero RPM+ URC – QAP
10:15 – 10:45	Coffee Break
10:45 – 11:20	DISCUSSION AND SUMMARY – Improving Treatment A
11:20 – 11:40	Improving Treatment B – Refugees, Accredited Drug Dispensing Outlets and Severe Malaria UNHCR RPM+ Dr. Patrick Kachur
11:40 - 12:25	DISCUSSION AND SUMMARY – Improving Treatment B
12:25 – 13:00	Cross-Cutting Issues – IEC, Operations Research, Private Sector Partnerships Andrew Makono Susan Omari
13:00 – 14:00	Lunch
14:00 – 14:30	DISCUSSION AND SUMMARY – Cross-Cutting Issues

14:30 – 14:50	MONITORING AND EVALUATION OF PMI 1 Dr. Patrick Kachur
14:50 – 15:20	DISCUSSION AND SUMMARY – Monitoring and Evaluation of PMI 1
15:20 – 15:35	Management, Coordination and Communication of PMI –Ways to Improve It – Discussion Dr. René Salgado
15:35 – 16:00	Next Steps and Follow Up ALL
16:00 – 16:10	Closing Remarks Dr. Alex Mwita Manager National Malaria Control Programme Ministry of Health and Social Welfare

**ANNEX 2. RPM PLUS CONCEPT PAPER FOR ACT DISTRIBUTION THROUGH  
ADDOS**

**Management Sciences for Health  
Rational Pharmaceutical Management Plus Program  
(RPM Plus)**

**Support to Malaria Control in Tanzania  
US President's Malaria Initiative**

**Distribution of Subsidized ACTs  
Through Accredited Drug Dispensing Outlets**

**May 2006**

**Final Draft**

## **BACKGROUND**

*Maduka ya dawa baridi* (DLDB) are authorized by the Tanzania Food and Drugs Authority (TFDA) to provide nonprescription drugs in the private sector. With estimated 4,600-plus stores nationwide, DLDB constitute the largest group of licensed retail outlets for purchasing medicines in Tanzania. For many common medical problems, such as malaria, diarrhea, and acute respiratory infections, a variety of factors encourage people to self-diagnose and medicate before visiting a government or registered non-government health facility. Since pharmacies are few in number and located almost exclusively in major urban areas, DLDBs are often the most convenient retail outlets from which to buy drugs. Although they provide an essential service, evidence indicates that DLDBs are not operating as had been intended; prescription drugs that are prohibited for sale by the TFDA are invariably for sale; product and service quality cannot be assured; and the majority of dispensing staff lack basic qualifications, training, and business skills. Regulation and supervision are also poor.

In response to these problems, the Ministry of Health/TFDA in collaboration with Management Sciences for Health's Strategies for Enhancing Access to Medicines (SEAM) Program<sup>1</sup> developed a pilot project to establish accredited drug dispensing outlets (ADDOS) that provide selected essential medicines and other health supplies in the Ruvuma Region. The goal of the ADDO project was to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural or peri-urban areas where there are few or no registered pharmacies. To achieve this goal, the SEAM program took a holistic approach that combined changing the behavior and expectations of individuals and groups, who use, own, regulate, or work in retail drug shops. For shop owners and dispensing staff, this was achieved by combining training, incentives, marketing and regulatory oversight with efforts to affect client demand for and expectations of quality products and services. The intent was to ensure that Tanzanians living in rural communities have access to quality non-prescription and a limited number of prescription drugs from regulated and properly operated drug outlets staffed by trained drug dispensers. ADDOS were also legally allowed to sell a limited number of prescription-only medicines that they could not sell in DLDB. After the SEAM project ended, USAID provided funds to support ADDO program roll out in Morogoro region where HIV/AIDS components will be integrated.

Malaria is the biggest public health problem in Tanzania. With the development of drug resistance to sulfadoxine-pyrimethamine, the Tanzanian government's National Malaria Control Program (NMCP) is implementing a revised malaria policy with artemisinin-based combination therapy (ACT) as the first-line treatment for uncomplicated malaria. The recommended ACT for the public sector is artemether-lumefantrine. The major challenge in implementing this policy is ensuring continuous availability of this ACT in rural and peri-urban areas at affordable prices. The ADDO represents the most appropriate and only legally authorized channel for accomplishing this in Tanzania. Currently, the National Malaria Control Programme (NMCP) recommends that first line treatment of malaria be extended to private retail sector outlets. However, ACTs are limited to registered pharmacies in large urban areas and are priced well beyond the reach of the rural and peri-urban communities who need them most. In some African countries efforts to expand access to free or highly subsidized ACTs beyond formal health facilities have included measures to make the drugs widely available through community health workers, maternal child health aides, and other minimally trained lay persons. In contrast to these approaches, ADDOS provide an opportunity to expand the availability of ACTs through a more controllable and legally recognized infrastructure and include provisions to limit wide scale abuse.

The United States Government will support Tanzania's malaria program through the President's Malaria Initiative (PMI), which seeks to *"dramatically reduce malaria as a major killer of children in sub-*

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<sup>1</sup> Funded by the Bill and Melinda Gates Foundation

*Saharan Africa.*<sup>2</sup> The overall five-year, \$1.2 billion initiative intends to rapidly scale up malaria prevention and treatment interventions such as promotion of insecticide-treated nets (ITNs), indoor residual spraying (IRS), prompt and effective case management of malaria and intermittent preventive treatment for pregnant women. The goal is to reduce malaria-related mortality by 50% after three years of full implementation in targeted countries. It is expected that malaria mortality reduction will be achieved if each selected country can reach 85% coverage of the most vulnerable groups with proven and effective interventions.

In 2005 the US Government conducted a rapid assessment in Tanzania and in March 2006 asked the Rational Pharmaceutical Management Plus (RPM Plus) Program to provide technical support for the implementation of the President's Malaria Initiative in this country. In the context of the national policies, the RPM Plus/President's Malaria Initiative program activities will support the NMCP's collaboration with the government's Medical Stores Department, the Tanzania Food and Drug Authority, the Office of the United Nations High Commissioner for Refugees, and ADDOs to improve the supply, rational use, and quality of antimalarials. (Scope of work: Annex 1)

ADDOs are private outlets through which such products will be marketed as part of a broader public-private health campaign against malaria. ADDOs can provide an ideal link with the Ministry of Health's nationwide malaria project and the Tanzania National Voucher Scheme—which supports sales of highly subsidized insecticide-treated nets for pregnant women and infants. Currently, the Mennonite Economic Development Associates (MEDA), the organization that provides the operational support for this program, has certified most of the ADDOs in Ruvuma Region to redeem the voucher for an insecticide-treated mosquito net. These ADDOs have been shown to have the business acumen and financial resources to handle these transactions.

The ACCESS Programme has carried out extensive research on the use of antimalarials in rural areas, and the findings show that up to 45% of the rural population would first seek treatment at a *duka la dawa baridi* for the first signs of malaria. Even if this behavior pattern were to change when ACTs are made available to public institutions, many clients will continue to rely on retail drug stores for their convenience and efficiency. A study in Rufiji District, where ACT has been widely available at public health facilities free of charge, showed that a substantial proportion of patients with malaria infection continued to seek treatment from DLDB. Furthermore, the quality of services offered by ADDOs over unregulated *maduka ya dawa baridi* was significantly increased by improving the knowledge and skills of dispensers and strengthening the regulatory system during the pilot phase of ADDO introduction in Ruvuma Region. Because of their location in rural and peri-urban areas, providing subsidized ACTs through ADDOs has several advantages including:

- Ensuring expanded access to effective malaria treatment because 75% of the population is rural and poor, where expensive private pharmacies in urban areas are not accessible
- Increasing early malaria treatment for children under five who would otherwise be taken to public health facilities that are often far away, resulting in treatment delays
- Discouraging the rural population from continuing to purchase antimalarial monotherapies and products that are no longer effective, but are easily available and much less expensive.

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<sup>2</sup> <http://www.whitehouse.gov/news/releases/2005/06/print/20050630-8.html>



- Enhancing the appropriate dosing and delivery of genuine quality-assured ACT products in rural areas
- Providing a platform for policy makers and donors to engage the private sector in a strategy to achieve full coverage of ACTs use and creating more incentive for the ACT manufacturer to tap into this high-potential and expanding ADDO market.

Considering these comparative advantages, ADDOs are well positioned to significantly contribute to the success of the President's Malaria Initiative in Tanzania. (ADDOs program description: Annex 2)

### **Program Description**

This initiative is meant to guide policy makers in developing strategies to expand access to ACTs by using the private sector to supplement the current public-sector supply system. In the context of the President's Malaria Initiative, it is proposed that the private sector will support malaria control and prevention in Tanzania by providing ACTs through ADDOs in both Morogoro and Ruvuma regions. To accomplish this, RPM Plus will work with other partners such as the IHRDC/ACCESS Programme and Mennonite Economic Development Associates to support the NMCP in delivering ACTs to ADDOs. RPM Plus is already providing technical assistance to the TFDA for the ADDO initiative and Mennonite Economic Development Associates currently support ADDO business development and management. The IHRDC/ACCESS Programme is supported by the Novartis Foundation for Sustainable Development with technical direction from the Swiss Tropical Institute.

There are 210 ADDOs in the Ruvuma region and about twice that number will be established in the Morogoro region by the end of the USAID-funded ADDO roll out in July 2007. ADDOs are largely situated in rural areas where the majority of the population lives. Unlike registered pharmacies, ADDOs generally serve low-income earners or those who have no stable income at all. The intervention will cover about 2.9 million inhabitants in the two regions, which is about 2.8% of the total Tanzanian population. It is estimated that 25 to 40%<sup>2</sup> of the population in the two regions will continue to go to an ADDO or to a *duka la dawa baridi* first to seek treatment for early symptoms of what they think is malaria. Thus, in Ruvuma and Morogoro, about 1.25 million people are expected to use this service.

The President's Malaria Initiative will procure an estimated US\$ 300,000 worth of artemether-lumefantrine from Novartis for supply through ADDOs. RPM Plus will support the implementation of this strategy through a comprehensive set of activities described below.

#### **1. Support policy change for TFDA to deregulate artemether-lumefantrine and incorporate it into the ADDO list of approved essential medicines.**

The decision to make all ACTs medicines available over-the-counter (OTC) as opposed to prescription only medicine (POM) is a government policy decision. In the past, TFDA allowed sulfadoxine-pyrimethamine and amodiaquine to be dispensed without a prescription to encourage early treatment of uncomplicated malaria at home and to comply with government policy. Removing sulfadoxine-pyrimethamine as the first-line drug for malaria treatment will require TFDA to replace it with an appropriate ACT. This means deregulating artemether-lumefantrine as a prescription-only medicine to become an over-the-counter product.

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<sup>2</sup> This is based on DLDB use in Rufiji District AFTER introduction of free ACT at public health facilities.

The new NMCP guidelines<sup>3</sup> already list ADDO outlets as an avenue for accessing the new ACTs. RPM Plus will work closely with NMCP and TFDA to ensure implementation of this policy in the ADDO outlets.

RPM Plus will also work with the TFDA to include these malaria treatment policy changes in the revised ADDO dispenser's training manual and also collaborate with TFDA to incorporate all ACTs registered by TFDA into the ADDO list of approved essential medicines.

**2. Develop the ADDOs' capacities to implement the new malaria policy related to artemether-lumefantrine storage, inventory control, and reporting.**

Training both dispensers and owners is a key requirement for the accreditation process for ADDOs and for improving the pharmaceutical services they provide. Dispensers' training covers good dispensing practices; symptoms and treatment of common diseases; code of ethics for ADDO dispensers; and laws, regulations, and guidelines for ADDO operation. The ADDO training also includes topics on communication, counseling, and family planning. The owners' training covers sessions on small business development, inventory management, sales and marketing strategies, and bookkeeping.

ADDO owners and dispensers in the two regions will be trained on the new malaria treatment policy before the introduction of ACTs into ADDO outlets. The training sessions will incorporate new information on inventory management, as the product shelf life is only two years; adverse drug reaction reporting; and monitoring and evaluation. In addition to the ADDO dispensers and owners, the district drug therapeutic committees, division and ward councils, and other local stakeholders will receive orientation on the new policy.

**3. Help implement the NMCP communication strategy to promote the access of artemether-lumefantrine through ADDOs in the Ruvuma and Morogoro regions.**

The NMCP has developed a national communication strategy for malaria. RPM Plus will work with NMCP to ensure that the strategy includes information to communities about the distribution of artemether-lumefantrine by ADDOs. The messages will include information on the new product presentation and therapeutic quality, the distribution sites, and product prices. The messages will be disseminated through local sensitization events, local radio programs, and communication materials already developed by NMCP and other partners, such as ACCESS, that will be adapted for ADDO outlets in Ruvuma and Morogoro.

**4. Help NMCP and partners procure and distribute artemether-lumefantrine to ADDO outlets located in Ruvuma and Morogoro regions.**

**4.1 – Procurement**

The World Health Organization/United Nations Children's Fund will procure the initial artemether-lumefantrine orders for ADDOs. Efficient port clearance and transportation to the designated general ADDO wholesaler(s) is needed to assure that the tax-exempt products are safely delivered to ADDO outlets.

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<sup>3</sup> United Republic of Tanzania. Ministry of Health. Diagnosis and Treatment of Malaria: Orientation Guide for District Trainers. Malaria Control Series 10, July 2005.

To help quantify the amount of ACTs needed to cover the number of people seeking malaria treatment at ADDOs, a number of assumptions have been made: there are 210 ADDOs in five districts of Ruvuma region and in Morogoro region there are 67 ADDOs in Ulanga and 140 in Kilombero, with additional ADDOs established in Morogoro region by July 2007. The total population in these two regions is 2.9 million; an estimated 45% of this population using the ADDO services would represent 1.42 million potential clients. The percentage of malaria cases in this segment of the population is estimated at 65%, therefore about potential 925,000 will be patients seeking malaria treatment in ADDO outlets by July 2007. Among these patients, 230,000 would be children under five years (25% of the population). Based on these overall estimates detailed discussions will determine more accurate estimates of the number of ACTs doses needed and the clients served in the two regions.

In addition, RPM Plus will continue to use routine malaria treatment data from the different ADDO outlets to adjust the quantification for the phased implementation of artemether-lumefantrine in the Ruvuma and Morogoro ADDOs. This activity will be integrated into the overall monitoring system to monitor the availability, rational use, and pricing of artemether-lumefantrine in the ADDOs.

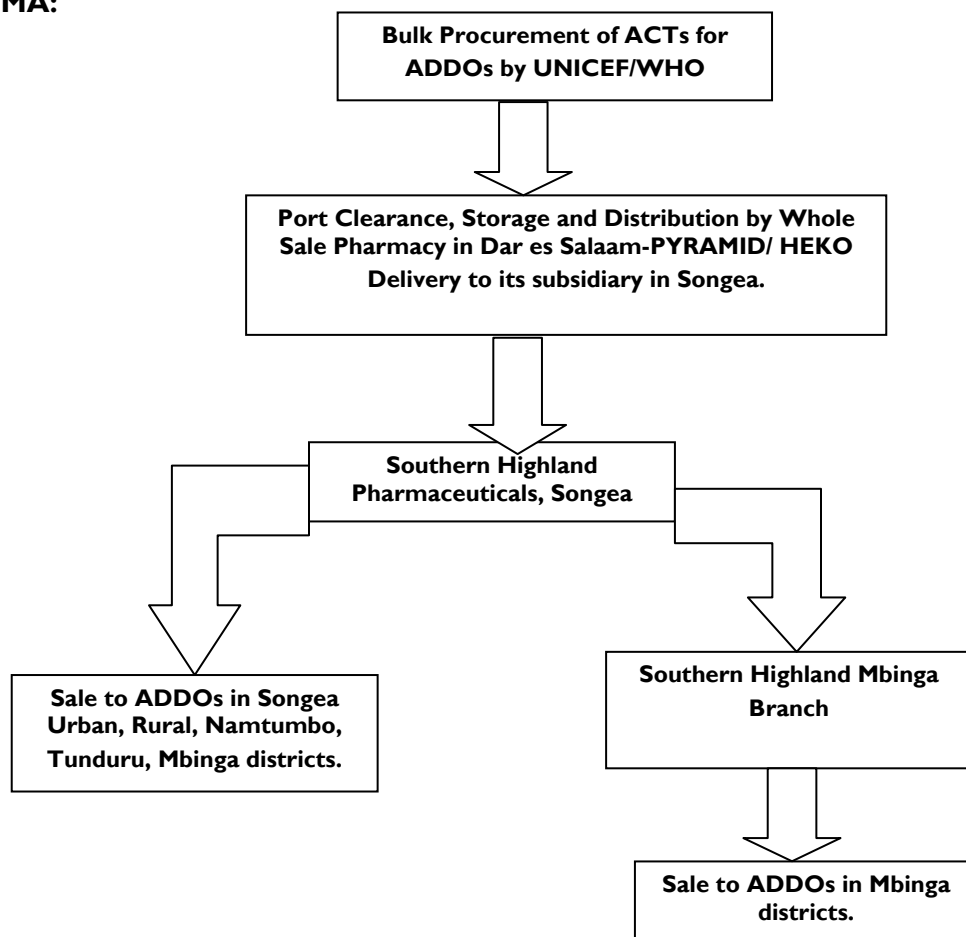
For the overall procurement and distribution of artemether-lumefantrine in Ruvuma and Morogoro regions, RPM Plus's proposed approach is conceptualized in the flow chart presented on the next page—

## **4.2 Distribution**

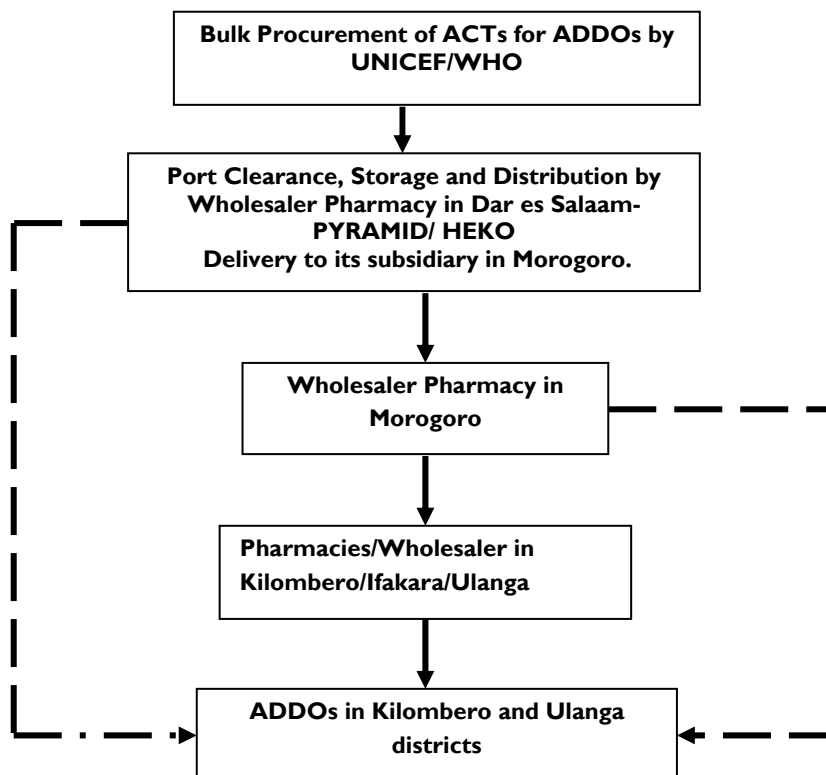
The location of ADDOs is in mainly rural and peri-urban areas, and is in close proximity to their clients. Therefore, ADDO outlets complement private pharmacy locations that sells branded ACTs in urban settings. ADDO clients represent the segment of the market for low income households while private pharmacy clients are usually from households with a higher purchasing power. The addition of ADDOs to the private pharmacies for increased geographical access for ACTs will allow patients from both segments of the market to benefit from early and effective treatment of malaria and reduce its related morbidity and mortality.

ADDOs are currently procuring their medicines from private pharmaceutical wholesalers and do not receive their supplies from the government's Medical Supply Department. Artemether-lumefantrine distribution would follow the existing ADDO supply chain for getting medicines to ADDO outlets. Some prerequisites must be addressed before ADDOs can distribute artemether-lumefantrine such as negotiations on pricing, storage, and incentives with the major wholesalers that supply ADDOs in Ruvuma and Morogoro and mapping of their distribution routes to include ACTs into their existing distribution network.

**IN RUVUMA:**



**IN MOROGORO:**



#### **4.3 Pricing mechanism for ACT sales in ADDO outlets**

The ACTs pricing policy in ADDOs will depend on the Government of Tanzania's decision on the level of subsidy to be applied to artemether-lumefantrine in the public sector. This level is not yet determined, but there are suggestions that the subsidized price should be close to the current sulfadoxine-pyrimethamine price of TSH300 or approximately USD 0.30. Actual price of ACTs in ADDO outlets would probably fall between what is offered in the public sector and those branded ACTs in the private commercial market.

The artemether-lumefantrine pricing policy in ADDOs will not only take into consideration the level of subsidy in the public sector but also other key elements such as: 1) the partial recovery of transport related costs and pharmaceutical services by ADDOs and their wholesalers, and 2) the appropriate funding by the Government of Tanzania and its partners to support the subsidy portion of the artemether-lumefantrine price.

The subsidy portion will be the difference between what patients will pay to buy a treatment of artemether-lumefantrine in ADDOs and its "all inclusive cost" related to the product's procurement, distribution, and promotion costs combined with a reasonable margin for ADDOs and their distributors. Without a minimal profit margin generated from the ACTs sales, ADDOs will find no incentive to make these products available in their outlets and depending on the cost proposed by the manufacturers, the subsidy portion will be more or less expensive to support by the Government of Tanzania and its partners.

It is also likely that other cheaper generic varieties of ACTs will find their ways into the ADDO outlets and they would be much more attractive as they would probably fetch high profit margins.

However, the final proposed price will be jointly determined by the various ADDO stakeholders under the NMCP's lead and considering the Government of Tanzania directives.

#### **5. Strengthen the ADDO monitoring and evaluation system to track artemether-lumefantrine distribution, quality, and rational use in collaboration with NMCP, TFDA, and district authorities.**

The shorter shelf life of ACTs (two years) is complicating pharmaceutical management by requiring more frequent procurement and distribution schedules to assure continuous availability and stricter inventory management to allow the redistribution of product among sites when needed to avoid expiration. Record-keeping systems already exist within ADDO outlets that include drug registers where all sales are recorded, inspection reports, expiry forms, and a store ledger. All these tools will provide data to track inventory and monitor commodity dispensing at the ADDO outlets that can then be used at the local and central/regional level to improve product availability.

The TFDA, NMCP, and local authorities will jointly conduct inspections of the ADDOs to assess the storage practices and product quality while reviewing the dispensing services. Possibly, adopting different packaging than that in the private sector to help the TFDA inspectors differentiate between ACTs in the private pharmacies to local authorities. The analysis of the consumption data generated by the tracking system can be combined with the supervision of ADDOs and periodic use of mystery clients to ensure periodic monitoring in ADDO outlets sites.

RPM Plus will collaborate with partners in Tanzania to develop monitoring and evaluation activities and strengthen the routine reporting system used to track ACTs. These collaborative activities will also include community adverse drug reaction (ADR) monitoring for ACTs with the Ifakara Health and Research and Development Center and how to expand the approach for ADDOs.

The TFDA and regional authorities have anecdotal evidence from that the ADDO program has so far been successful in substantially reducing pilfering of essential medicines from public health facilities for resale into the private sector through three main interventions—

- Allowing the ADDOs to store and sell essential prescription medicines that are included in the essential drugs kit for rural public facilities.
- Promoting behavior change of ADDO owners and dispensers by emphasizing their ethical responsibilities to follow requirements to provide quality services.
- Facilitating more efficient and frequent inspections and reporting by decentralizing regulation to district drug therapeutic committees and district and regional pharmacists

The TFDA is determined to maintain these achievements in reduced drug leakage from the public to the private sector by further strengthening regulatory functions and inspection/reporting mechanisms, and continuing education in both skills and behavior change.

ACTs will represent the first drug incorporated into the ADDO system for which a substantial price subsidy will be necessary for it to compete effectively with outdated antimalarial treatments and artemisinin monotherapies. The TFDA has developed systems for monitoring, evaluating and tracking ADDO products, and these will be strengthened to accommodate the introduction of ACT. In particular, monitoring for leakage and discouraging the sale of subsidized products intended for rural ADDOs at urban pharmacies or through other illegal channels will require enhancing these systems.

#### **6. Develop a management structure and coordination mechanism.**

RPM Plus is hiring a Senior Program Associate in Tanzania who will work closely and coordinate with the President's Malaria Initiative team, NMCP, TFDA, and other partners at the national level, and stakeholders at the district level including councils, district medical officers, ward and village executive officers in Ruvuma and Morogoro regions. RPM Plus will coordinate activities with Ifakara Health Research and Development Center (IHRDC). The RPM Plus Tanzania team will be supported by the regional technical malaria team based in Nairobi, and the RPM Plus malaria team based in Arlington, Virginia.


## **CONCLUSION**


The ADDO program can best be described as a Government of Tanzania-driven initiative that uses retail outlets to maximize access to pharmaceutical services for rural and peri-urban Tanzanians. In the context of the President's Malaria Initiative, ADDOs represent an opportunity for expanding the distribution of subsidized ACTs in the private sector and reaching the poorest and most marginalized populations. This initiative has a unique potential for reducing malaria morbidity and mortality in Tanzania by creating synergy through the combination of multiple interventions.

### ANNEX 3. RPM PLUS PRESENTATION AT PMI CONSULTATIVE MEETING


**Support to  
Malaria Control  
in Tanzania  
US President's  
Malaria Initiative**


**NMCP/PMI  
Consultative Meeting,  
Dar es Salaam, 31<sup>st</sup>  
May 2005**

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 **USAID**  
FROM THE AMERICAN PEOPLE

**Distribution of ACTs through a Private Sector  
Accredited Drug Dispensing Outlets (ADDO)**



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## BACKGROUND

Where did the ADDO initiative  
come from?



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The overall problem:  
How to increase access to and  
rational use of essential quality medicines?



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## Duka la dawa baridi (DLDB) problems:

- Limited list of authorized drugs to sell
- Inadequate sources of medicines & commodities
- Medicines stored improperly
- Lack of qualified dispensers
- High prices
- Inadequate regulation and supervision



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## The solution:

- Transform DLDBs into Accredited Drug Dispensing Outlets through a comprehensive training program in pharmaceutical and business management.
- Provide a limited range of high-quality prescription only essential medicines at reasonable prices
- Quality ensured through a combination of government accreditation and regulation with routine monitoring/inspection by district/local authorities.



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## Potential results to PMI investment in ADDO (1)

- Expanded access to malaria medicine for home based treatment to reach GOT and PMI targets
- Ensure high quality products in communities
- Improved rational medicine use
- Additional pool of trained human resources
- Enhanced regulatory control in the private sector



## Potential results to PMI investment in ADDO (2)

- Increased opportunity to reach the marginalized and poor communities
- Potential for achieving health outcomes through combined intervention/programs.
- Enhanced sustainable infrastructure for public health service delivery using public-private mix.
- Support government & health sector reforms
- Stimulated economic development



## Current status of ADDO program

- Continued GOT commitment – financial and political.
- Planned nationwide roll out. Roll out under way in 3 regions- Rukwa, Mtwara (GOT funded) and Morogoro (USAID-funded).
- 210 ADDO outlets fully established in Ruvuma under MSH/SEAM, 54 established in Ulanga and 125 to be ready by mid-July 2006 in Kilombero.
- DANIDA-funded project evaluation carried out.
- Plans to institutionalize training of ADDOs dispensers/ owners underway.



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## PMI Plan-Where are we?



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## RPM Plus Activities

- On going support to NMCP for the establishment and meetings of the ACT implementation working groups
- Supported the design of a detailed operational plan for artemether-lumefantrine storage and distribution
- Initiated the stores and inventory management training of regional and district pharmacists.
- Planning activities for the Pharmacovigilance /ADR Workshop with TFDA and stakeholders in July 2006.
- Recruitment of a Senior Program Associate for PMI.
- Detailed work plan for year I completed.
- Draft concept paper submitted to USAID for Novartis and other partners.



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## ACTs Delivery Through ADDO Outlets



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## Proposed strategy (1)

- Support national authorities for ACT deregulation
- Orient ADDO outlets and local stakeholders to implement new malaria policy.
- Work with NMCP to implement communication strategy for ADDO.

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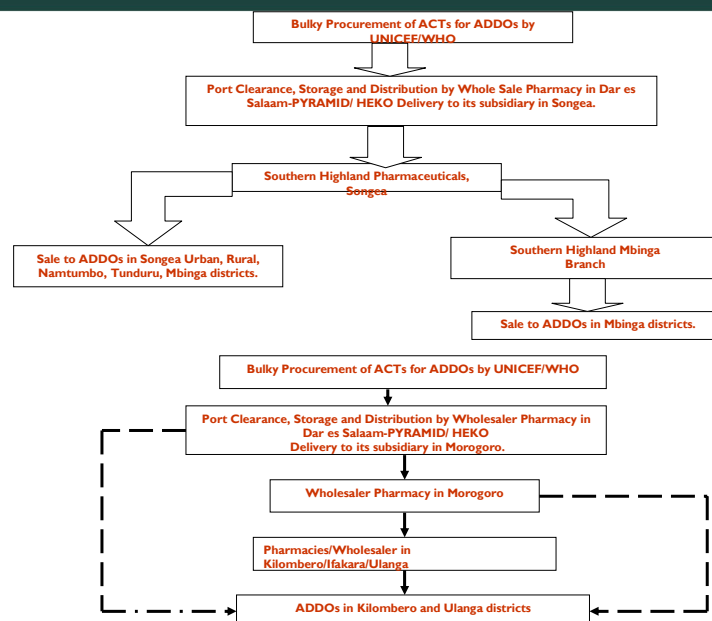
## Proposed Strategy (2)

- Develop ACT distribution with private wholesalers.
- Work with MOHSW/NMCP and PMI team to develop a pricing policy/mechanism of ACT in ADDOs.
- Work with TFDA/NMCP to strengthen ADDO M&E and inspection systems and develop ACTs tracking system at all levels of delivery.



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## Challenges

- Pricing and long-term funding of subsidized ACT on the basis of public health benefit vs. commercial interest.
- Comprehensive coordination and management
- On going and expanded supervision and inspection



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## What is for Year 2?

- Consolidate ACT delivery in ADDO outlets and expand to new ADDO outlets for rest of districts in Morogoro region.
- Develop M&E infrastructure for the ACTs in ADDO program.
- Support TFDA in developing and implementing a comprehensive national ADDO roll out strategy.



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## What is for Year 2?

- Strengthen pharmacovigilance/ADR reporting in both public and private sectors.
- Support NMCP in working with MSD for distribution and supervision operations.



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